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Hirulog™ vs. Heparin During Percutaneous Transluminal Coronary Angioplasty in Patients with Post-Infarction Angina: Results of the Myocardial Infarction Arm of the Hirulog Angioplasty Trial

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Acute intervention for recurrent angina following an acute myocardial infarction continues to present as a therapeutic challenge to the physician. Standard anticoagulation using heparin during PTCA in patients with post infarction angina is associated with a 16% incidence of abrupt vessel closure and an 11% incidence of death, CABG, and recurrent MI. The ability of Hirulog™ (BG8967), a direct thrombin inhibitor, to improve PTCA outcome was compared in a double blind fashion to heparin in the Phase III Hirulog Angioplasty Trial. Clinical and angiographic results from the post infarction subgroup (n = 635) will be reported. Patients were randomized to either Hirulog™ (2.2 mg/kg bolus and 1.0 mg/kg/hr infusion) or heparin (175 U/kg bolus and 15 U/kg/hr infusion). Additional boluses were administered in order to maintain a minimum activated clotting time of 350 seconds. The primary endpoint was procedural failure (impending or established abrupt vessel closure, bypass surgery, recurrent MI, or death) with a secondary endpoint of major hemorrhage. The event rates in this 635 patient subgroup were: Death 0.8% (n = 5), Emergency Bypass 2.2% (n = 14), Recurrent Myocardial Infarction 2.5% (n = 16), Abrupt vessel closure 5.8% (n = 37), and Major Hemorrhage 6.8% (n = 43).

In summary, this study will determine: (1) whether Hirulog™, a direct thrombin inhibitor, is superior to heparin when used during PTCA in patients with post-infarct angina and (2) the overall safety profile of Hirulog™ in this subgroup.

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A Prognostic Factor in Coronary Artery Disease (CAD): Platelet-Dependent Thrombin Generation in Patients with CAD

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We examined platelet-dependent thrombin generation in patients with coronary artery disease (CAD). Thrombin generation was measured according to the method of Aronson et al (Circulation, 1992). 0.5 ml of platelet rich plasma (PRP, 15×10^4 /ml) was prepared, and 40 mM of CaCl₂ was added to start clotting. 0.5 mM of S-2238 was added to each sample in a microtiter plate every 10 min, and the plate was read kinetically at a wavelength of 405 nm on a microtiter plate reader. The patients with CAD divided into 3 groups. Thrombin generation 20 min after CaCl₂ addition is:

Control (n = 12)	48 ± 10(mOD)
Stable angina (SAP) (n = 15)	79 ± 27
Unstable angina (UAP) (n = 15)	**562 ± 155
Acute myocardial infarct (AMI) (n = 43)	**440 ± 269

**p < 0.01 compared to SAP

The patients with UAP and AMI showed marked increase in thrombin generation compared to SAP and control subjects. AMI patients with severe coronary artery disease (Group B) showed higher levels of thrombin generation (Group A, Gensini score < 32: 382 ± 248 mOD vs Group B, Gensini score > 31: 578 ± 238 , P < 0.05). LVEF of group A is significantly higher than that of group B (P < 0.05). These findings indicate that patients with UAP and AMI have an evidence of hypercoagulable states and that platelet-dependent thrombin generation may play an important role in pathophysiology of UAP or AMI, and may be a prognostic factor in CAD.

1006-45

Regression of Infarct-Related Coronary Lesions on Aggressive Lipid Lowering Treatment in Patients After Recovery from Acute Myocardial Infarction

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Considering of remained active nature of infarct-related lesion (IRL) early after recovery from acute myocardial infarction (AMI), a prospective study was undertaken to determine whether IRL exhibits more regression on aggressive lipid lowering treatment. Fifty patients (pts), 34 hyperlipemic (HL) and 16 normal lipids (NL), aged ≤ 65 year with coronary diameter stenosis >25% were followed monthly. LDL-cholesterol (LDL-C) level was aimed to control below 130 mg/dl in HL patients on strict diet and pravastatin 10–30 mg/day, also LDL-apheresis in a patient with familiar hyperlipemia. Repeat coronary angiography was performed in average 14 months after AMI onset, and al-

together 142 lesions from 34 HL and 16 NL were analyzed quantitatively using cine-densitometry. Lesions which PTCA wire crossed were separately assessed. Average serum LDL-C levels improved from 166 to 117 mg/dl on drug and diet (p < 0.001) in HL. Seven out of 92 non-IRL (7.6%) exhibited progression defined as ≥0.5 mm decrease of minimum lesion diameter, and 9 IRL (9.8%) did regression ≥0.5 mm increase. Whereas thirty five IRL showed significantly more incidence of regression (9 sites, 25.7% p = 0.021) and similar rate of progression (3 pts, 8.6%). An improvement of LDL-C/HDL-C ratio was more prominent in patients with IRL regression compared with those showing progression or no change (p < 0.05).

Thus the IRL was found in favor of more regression than non-IRL, and the magnitude of lesion regression can be expected according to the effect of lipid lowering treatment in patients after AMI.

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Pericardial Physiology and Pathology; Cardioversion; Diastolic Function; Thyrotoxicosis

Wednesday, March 22, 1995, Noon–2:00 p.m.

Ernest N. Morial Convention Center, Hall E

Presentation Hour: 1:00 p.m.–2:00 p.m.

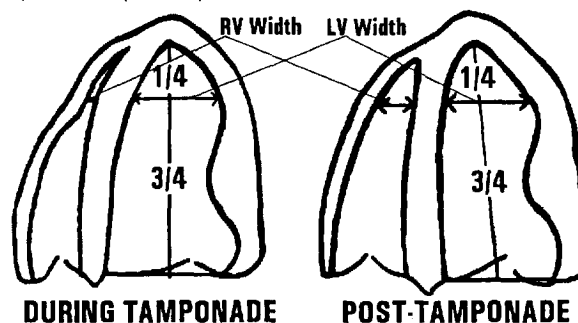
1007-16

Quantitation of Apical Right Ventricular Collapse in Tamponade: A Diagnostic Improvement

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Right ventricular (RV) collapse, a popular echocardiographic sign of tamponade is a subjective call with no precise criteria. RV collapse is usually diagnosed by early diastolic "dimpling" or local concavity of RV anterior wall in parasternal views. In 15 patients with pericardial effusion studied (A) during tamponade, and (B) after relief of tamponade, we noted that definite such "dimpling" could be seen in only five out of ten cases, while in six patients parasternal window was inadequate. In contrast, the apical four-chamber view could be obtained in all 15 patients. In this view we made several RV measurements including various transverse RV dimensions, RV area and ratios of these to the corresponding LV measurements.

Results: LV width/RV width ratio at the junction of the apical 1/4 to basal 3/4 of LV length showed the best separation between tamponade and post-tamponade values (p < 0.005). Using a cut-off value of LV width/RV width ≥3 as indicative of tamponade. This criterion showed no overlap between tamponade and post-tamponade values.



Conclusion: Ratio of LV width to RV width ≥3, measured at the junction of apical 1/4 with basal 3/4 of LV, is a promising sign of tamponade, reflecting selectively greater collapse of near-apical region of RV in tamponade.

1007-17

Demonstration of Pericardial Constraint in Chronic Heart Failure

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Pericardial constraint may be an important feature in chronic heart failure (CHF). We hypothesized that baseline pericardial constraint could be inferred if left ventricular end-diastolic volume (LVEDV) paradoxically increased during lower body negative pressure (LBNP), as a consequence of abolition of constraint with an increase in the left ventricular transmural and transeptal pressure gradients.

Methods: 11 patients with CHF and left ventricular ejection fraction <35% (age 34–82, mean 51.5 years; 8 male, 3 female) were compared with 6 healthy controls (age 31–61, mean 50.5 years; all male). Radionuclide ven-